PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Term perinatal mortality audit in The Netherlands 2010-2012: a population based cohort study
AUTHORS	Eskes, Martine; Waelput, Adja J.M.; Erwich, Jan Jaap H.M.; Brouwers, Hens A.A.; Ravelli, Anita C.J.; Achterberg, Peter W.; Merkus, Hans (J).M.W.M.; Bruinse, Hein W.

VERSION 1 - REVIEW

REVIEWER	Jason Gardosi Perinatal Institute Birmingham, UK
REVIEW RETURNED	23-Jun-2014

GENERAL COMMENTS	This is an important study detailing the introduction of a national programme for perinatal audit and the observations which were made on its selected category for investigations, term perinatal deaths. Such audit can be a rich source of learning and the authors describe a method which was successfully implemented over a relatively short time period. I have the following queries / comments / suggestions to consider prior to publication: 1. It would be useful to get some general idea what the cases were actually audited against. On Page 5 – line 54/55, the authors talk about formal guidelines but there is no reference about which ones were used, where they are available, how comprehensive they are in covering care of pregnancies at term etc. It needs to be clear to the international BMJ Open readership that agreed guidelines, preferably national, are a prerequisite, esp. as they don't exist in every country. 2. Page 9 – line 5 ff and Table 4 - the statement that 'probable ' factors were halved in 2012 implies that this is significant and related to the audit process. This should be supported by statistics, and to do this will require also a year by year listing of the cases with SSFs 'unlikely' to be related to deaths 3. Similarly - page 10 – lines 17 onwards and in the abstract - the authors state that the mortality decreased during the three years of the audit from 2.3 to 2.0 per 1000, apparently suggesting a causal association attributable to the audit process. Such a claim would seem to contradict the statement in 'Methods' that the report is descriptive only. However if rates are quoted to imply improvement due to the audit, then more information is required to support the claim, including confidence intervals and tests of statistical significance.

	4. p10, line 31: Independent chair person – I suggest the authors describe in more detail the role of the chair for those who want to adopt this model 5. Table 6: More information would be useful to describe the cohort which was reviewed. What proportion of mothers were obese? How many babies were SGA? 6. Page 11 – the authors present comparative rates of avoidable factors or suboptimal care factors in other Dutch audits and from different countries, but do not discuss possible reasons for the different results. In particular, it would be appropriate to examine whether, compared to external review, their method of internal review with external chair was more or less likely to identify SSFs and avoidable factors. 7. Linked to the last point: apart from describing a method which was successfully implemented - do the authors have confidence that it is also accurate, considering the small proportion of cases (8%) it was able to identify as 'probably' avoidable? Minor points 8. Page 9 Recommendations: - 603 were given – it would be useful to know in how many of the 707 cases these were made. How did they relate to the 376 cases with SSF? 9. Abstract: 'Antepartum low risk selection decreased from 21% in 2010 to 16% in 2012'. This could be expressed more clearly – do the authors mean that fewer pregnancies resulting in perinatal deaths were designated as low risk? 10. Page 8 line 33: 'without motivation' – what does this mean?

REVIEWER	Kari Klungsøyr University of Bergen, Norway and Norwegian Institute of Public Health, Norway
REVIEW RETURNED	14-Jul-2014

GENERAL COMMENTS	Although I have marked "Yes" for most questions above, I think several points could be improved. The English should be improved throughout, also in the abstract. Abstract: Some sentences miss words, e.g in "Setting". Use "cases of perinatal death" instead of "cases of perinatal mortality", and "term perinatal deaths" instead of "term perinatal mortality cases". I find the phrase "primary care supervision at start of labour" strange. I guess the "antepartum low risk selection for primary care" is supposed to be a selection of women who are supposedly able to go through the entire delivery in primary care (although, of course, if complications arise, she may need to be transferred to hospital). I

	would suggest saying “antepartum low risk selection for primary care delivery”. I also guess that the primary care workers (midwives and/or general practitioners) actively support the woman during delivery, and not only “supervise”. Rewrite “Of all 1102 term perinatal mortality cases (2.3 per 1000) for 86% (943) of cases extensive data are registered and of 64% (707) standardized audit results are documented” to e.g.: “Of all 1102 term perinatal deaths (2.3 per 1000), extensive data were registered for 86% (943) of cases, and standardized audit results were documented for 64% (707). Rewrite: “In the study period 8% of all audited cases had a probable relation between the SSF and perinatal Death” to e.g. “In the study period, there was a probable relation between the SSF and the perinatal death for 8% of all audited cases.” "Simultaneously, term perinatal mortality decreased from 2.3 to 2.0 per 1000 births." I would suggest that 95% confidence intervals around these proportions are given, or that the rates in 2010 and 2012 are compared by chi square tests, especially since the conclusion states that the audit possibly contributed to the decrease IN (not “of”) term perinatal mortality. One of the main outcome measures defined in the abstract is "perinatal death classification". This is shown by the distribution of fetal and neonatal deaths as well as by the distribution of underlying cause of death according to the Tulip classification. However, in spite of this being a main outcome measure, the results are hardly discussed. Also, in the Methods, three classification systems are mentioned used (Wigglesworth, ReCoDe and Tulip classifications), however, only the results from the Tulip classification are shown. The authors might discuss the distribution of causes of death with other studies of term perinatal deaths. It might also be interesting to see the results of the different classification systems, or at least an explanation for only showing the Tulip results. Tables need improvement: Tables should provide enough information so that they can be read alone, and readers should not need to look for explanations in the text. Formats and spelling should be checked. All table headings should begin with a capital letter. All abbreviations should be explained in footnotes or in headings, e.g. PRN, PRN-Audit, and PARS in Table 1, 6a and 6b. Table 2b: Give the categories names that are more informative. Here again, the reader needs to read the text in order to understand that “usual care” means “deviation from usual care” and that “guidelines” means that guidelines were either not followed, or that local protocols were missing. Table 2a: As much as 53% of cases had 1 or more SSF. This should allow for a more detailed categorization, based on the distribution of numbers of SSFs per case. The wording of Table 2a's heading need to be corrected. (e.g.Number of substandard factors (SSF) per case in term perinatal mortality.) Table 3: Tulip-classification of UNDERLYING CAUSE OF DEATH in term perinatal mortality cases, by main group and placental subgroup (2010-2012) Table 5: "care type supervision at start of labour". Do you mean Level of care at start of labour? Does primary care include home delivery? If so, this should be noted

	in footnotes, and probably also in the Methods (the Netherlands has a large proportion of home deliveries compared to many other European countries). There are many tables. The authors might consider showing some results, for instance Tables 2a and b as a figure, for instance a bar chart, (but as mentioned for 2a, with more categories of SSFs) I miss some more details, perhaps as a table (if some of the present tables could be changed to figures) about the links between the SSFs and the recommendations made to improve quality of care. A total of 603 recommendations were given, and it would be interesting to see these grouped and tabulated, and the relations between the SSFs and the recommendations discussed. Term perinatal death actually also includes post term (23 post term deaths). The paper is inspiring, and it is impressing that the Netherlands has managed to get a national, systematic perinatal audit running throughout the country, where all perinatal cooperation groups participate. There is no mentioning about the cost of this program; that might be of interest. What about future plans: continuation, expansion to other indicators, evaluation? The paper needs language editing, and the tables need improvement. The authors should also consider to use figures instead of tables for some results, and also consider to tabulate groups of recommendations given. I also miss some discussion about the distribution of causes of death compared to other studies on causes of term perinatal death. The authors use the wording "term perinatal mortality", while in fact, also post term cases are included. This should be commented in the Methods. Finally, I would not state in the conclusion of the abstract that the audit possibly has contributed to the decrease in perinatal mortality without testing the significance of the decrease.

REVIEWER	Babill Stray-Pedersen Institute of clinical Medicine, University in Oslo and Division Women and children, Rikshospitalet, Oslo University Hospital Oslo Norway
REVIEW RETURNED	15-Jul-2014

GENERAL COMMENTS	The report from this new perinatal mortality audit registry is very interesting and deserves to be published. The study design is appropriate, and clearly described, but the results suffer from lack of proper statistics. and some statement are sort of misleading. In the abstract and results the declines observed are not significant. No p-values are given. The total term perinatal mortality increases from 2010 to 2011 and then falls. Actually the reduction in perinatal mortality from 2010/2011 to 2012 is significant (p=0.04), however a Type II error has been performed. A simple power calculation reveals a lack of sufficient power ($1-\beta = 0.3$) to presume a significant reduction in perinatal mortality. There are too many tables, some has the same information (like Table 2 and 4). The denominators are not given – only numbers and percentages making it difficult to calculate if there are real

	differences. The headings of the tables are also lacking accurate information. Some refers to PARS, some to PRN-Audit. Abriviations are lacing in the tables Table 1. no significance given Table 2a: Delete, all information given in Table 4. table 2b: There are 10 cases with more SSF, how does this show in the percentage?? Table 3. Autopsies were performed in 269 cases(38%) only and placenta biopsies in 544 cases(77%). How does this reflect in the table?? Table 4 gives information from PARS first part same as table 2. Probable relation to death per year: denumerators are lacking. Table 5 refer to PRN-audit data. Denominator in Primary care is lacking, but my calculation shown the trend is not significant. To state that it is a 24% decrease is sort of giving a wrong impression. Table 6a and b: why not in one table PRN,PARS and PRN -Audit?? The same information are given twice. Why is gestational age recorded differently. 6a: Total numbers in PARS and PRN are lacking. 6b: any relation ship between non-Caucasian ethnicity and birth weight <2000g?? How is fetal spelled???

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name Jason Gardosi
Institution and Country Perinatal Institute
Birmingham, UK
Please state any competing interests or state 'None declared': None declared

This is an important study detailing the introduction of a national programme for perinatal audit and the observations which were made on its selected category for investigations, term perinatal deaths. Such audit can be a rich source of learning and the authors describe a method which was successfully implemented over a relatively short time period.

I have the following queries / comments / suggestions to consider prior to publication:

Question 1 (reviewer 1):
It would be useful to get some general idea what the cases were actually audited against. On Page 5 – line 54/55, the authors talk about formal guidelines but there is no reference about which ones were used, where they are available, how comprehensive they are in covering care of pregnancies at term etc. It needs to be clear to the international BMJ Open readership that agreed guidelines, preferably national, are a prerequisite, esp. as they don't exist in every country.

Answer to question 1 (reviewer 1):
Formal guidelines are accessible at the websites of the professional organisations of the midwives (25 topics), gynaecologists (63), paediatricians (29) and general practitioners (3). Most guidelines are covering as well term pregnancies. The Foundation Perinatal Audit in The Netherlands (PAN) has collected all national guidelines in perinatology on her website www.perinataleaudit.nl. These guidelines are arranged by professional organisation and by subject http://www.perinataleaudit.nl/bibliotheek/richtlijnen/aandoeningen. The agreed referral list of primary care to secondary care (VIL, Obstetric Indication List) is also included (125 topics, translated in English in: Bleker OP, Hulst LAMvd, Eskes M, Bonsel GJ. Place of birth: evidence for best practice.

Bonnar J, Dunlop W, editors. Recent advances in Obstetrics and Gynaecology. London: Royal Society of Medicine Press; 2005. Page 77-100).
This information is added to the method section.

Question 2 (reviewer 1)
Page 9 – line 5 ff and Table 4 - the statement that 'probable ' factors were halved in 2012 implies that this is significant and related to the audit process. This should be supported by statistics, and to do this will require also a year by year listing of the cases with SSFs 'unlikely' to be related to deaths

Answer to question 2 (reviewer 1):
Table 4 is expanded with year by year numbers and p-values. Statistics (Chi-square) show just not a significant decline of cases with a probable relation to death (because of small numbers) during the years (p=0.060). Otherwise the cases with SSF not/unlikely related to death increased (p=0.028). We adjusted the text.

Question 3 (reviewer 1): Similarly - page 10 – lines 17 onwards and in the abstract - the authors state that the mortality decreased during the three years of the audit from 2.3 to 2.0 per 1000, apparently suggesting a causal association attributable to the audit process. Such a claim would seem to contradict the statement in 'Methods' that the report is descriptive only. However if rates are quoted to imply improvement due to the audit, then more information is required to support the claim, including confidence intervals and tests of statistical significance.

Answer to question 3 (reviewer 1):
Indeed the study is descriptive and no causal relation with decrease of perinatal mortality and audit can be proven in our study. But the coincidence of the significant increase of the cases with SSFs 'none/unlikely' related to the death and decrease of perinatal mortality suggests circumstantial evidence. Decrease of term perinatal mortality 2010-2011-2012 is significant ($p<0.00001$). We supplemented table 1 with p-values (Chi-square test and adjusted the text in the abstract, results and the discussion.

Question 4 (reviewer 1):
p10, line 31: Independent chair person – I suggest the authors describe in more detail the role of the chair for those who want to adopt this model

Answer to question 4 (reviewer 1):
We agree with your suggestion and describe in more detail the role of the chair in the methods section.

Question 5 (reviewer 1):
Table 6: More information would be useful to describe the cohort which was reviewed. What proportion of mothers were obese? How many babies were SGA?

Answer to question 5 (reviewer 1):
Table 5 was made to explore possible bias by comparing characteristics present in PARS and PRN-Audit with characteristics in the national perinatal registry (PRN). Besides that unfortunately BMI is not present in the PRN neither smoking of the mother.

Question 6 (reviewer 1):
Page 11 – the authors present comparative rates of avoidable factors or suboptimal care factors in other Dutch audits and from different countries, but do not discuss possible reasons for the different results. In particular, it would be appropriate to examine whether, compared to external review, their method of internal review with external chair was more or less likely to identify SSFs and avoidable

factors.

Answer to question 6 of referee 1:
We could only speculate about the origin of these differences, and comparison with studies from about 20 years ago is not quite correct;
The lower percentage of identified cases without SSF (thus higher percentage with SSF cases) in our study compared to earlier external audits can be a more critical assessment by professionals about their own delivered care. Otherwise these studies were 10 or more years ago and in the meantime many guidelines are developed as reference for SSF.
The lower percentage of a combined possible or probably relation in our study compared with earlier external audit studies can be (partly) a result of quality of care improvement during the past 20 years. Otherwise it would be desirable to examine whether, compared to external review, our method of internal review with an external chair was more or less likely to identify SSF's with possible/probable relation to the death.
However the LPAS study (ten years ago) was an external audit and showed the same result as our study with 9% cases with 'probably' relation with death. We added this in the discussion section.

Question 7 of referee 1:
Linked to the last point: apart from describing a method which was successfully implemented - do the authors have confidence that it is also accurate, considering the small proportion of cases (8%) it was able to identify as 'probably' avoidable?

Answer to question 7 (referee 1):
For a definite answer, comparison with a gold standard of assessing the number of avoidable cases should be done, which is not available. In our study the percentage of SSF that were probably related to perinatal death declined (just not significantly) over the years from 10% (n=23) to 5% (n=10) (p=0.060). The SSF cases without a relation to death increased (p=0.028) and the SSF cases with a possible relation to death did not change while the rate of cases with SSF remained also the same. In our view this can fit with a stable, consistent audit procedure. See the revised table 4. The text has been modified in the discussion section.

Minor points

Question 8 (reviewer 1):
Page 9 Recommendations: - 603 were given – it would be useful to know in how many of the 707 cases these were made. How did they relate to the 376 cases with SSF?

Answer to question 8 (reviewer 1):
In the 376 cases with SSF one or more SSF's were indicated: in 213 cases (57%) one SSF, in 73 cases (19%) two SSF's and in 90 cases (24%) three or more SSF's.
In 71% of all indicated SSF's (512/717) one recommendation is done, and in 6% (41/717) two and sometimes three recommendations. The text is supplemented in the results section.

Question 9 (reviewer 1):
Abstract: 'Antepartum low risk selection decreased from 21% in 2010 to 16% in 2012'.
This could be expressed more clearly – do the authors mean that fewer pregnancies resulting in perinatal deaths were designated as low risk?

Answer to question 9 (reviewer 1):
Indeed we meant that fewer pregnancies resulting in perinatal deaths were designated as low risk. On second thoughts we discovered that we made a mistake. The decrease appeared not significant (possibly because of small numbers), but the increase of secondary/tertiary level of care at start of

labour was significant (p=0.001). We revised the table and the results in the abstract, the summary and the result section.

Question 10 of referee 1:
Page 8 line 33: ‘without motivation’ – what does this mean?

Answer to question 10 of referee 1.:
We meant that in special circumstances it is better not to follow a guideline but then you must motivate your decision. We think this information is too much detail, so we deleted ‘without motivation’.

Reviewer: 2
Reviewer Name Kari Klungsøyr
Institution and Country University of Bergen, Norway
and Norwegian Institute of Public Health, Norway
Please state any competing interests or state ‘None declared’: None declared

Although I have marked "Yes" for most questions above, I think several points could be improved. The English should be improved throughout, also in the abstract.

Abstract:
Some sentences miss words, e.g in "Setting".

Answer:
We adjusted the text.

Use “cases of perinatal death” instead of “cases of perinatal mortality”, and “term perinatal deaths” instead of “term perinatal mortality cases”.

Answer:
We agree and followed your advise

I find the phrase “primary care supervision at start of labour” strange. I guess the ”antepartum low risk selection for primary care” is supposed to be a selection of women who are supposedly able to go through the entire delivery in primary care (although, of course, if complications arise, she may need to be transferred to hospital). I would suggest saying “antepartum low risk selection for primary care delivery”. I also guess that the primary care workers (midwives and/or general practitioners) actively support the woman during delivery, and not only “supervise”.

Answer:
We agree with your remarks and suggestions and revised the text in the abstract and the results.

Rewrite “Of all 1102 term perinatal mortality cases (2.3 per 1000) for 86% (943) of cases extensive data are registered and of 64% (707) standardized audit results are documented” to e.g.:
“Of all 1102 term perinatal deaths (2.3 per 1000), extensive data were registered for 86% (943) of cases, and standardized audit results were documented for 64% (707).

Answer:
We agree and revised the text in the abstract.

Rewrite: “In the study period 8% of all audited cases had a probable relation between the SSF and

perinatal Death” to e.g. “In the study period, there was a probable relation between the SSF and the perinatal death for 8% of all audited cases.”

Answer:
We agree and revised the text in the abstract.

"Simultaneously, term perinatal mortality decreased from 2.3 to 2.0 per 1000 births." I would suggest that 95% confidence intervals around these proportions are given, or that the rates in 2010 and 2012 are compared by chi square tests, especially since the conclusion states that the audit possibly contributed to the decrease IN (not “of”) term perinatal mortality.

Answer:

We added the results of chi square tests in table 1 and in the abstract.

One of the main outcome measures defined in the abstract is "perinatal death classification". This is shown by the distribution of fetal and neonatal deaths as well as by the distribution of underlying cause of death according to the Tulip classification. However, in spite of this being a main outcome measure, the results are hardly discussed. Also, in the Methods, three classification systems are mentioned used (Wigglesworth, ReCoDe and Tulip classifications), however, only the results from the Tulip classification are shown. The authors might discuss the distribution of causes of death with other studies of term perinatal deaths. It might also be interesting to see the results of the different classification systems, or at least an explanation for only showing the Tulip results.

Answer:
We give also the ReCoDe and Wigglesworth classification in table 3 and added results and discussion in the text.

Tables need improvement:
Tables should provide enough information so that they can be read alone, and readers should not need to look for explanations in the text. Formats and spelling should be checked. All table headings should begin with a capital letter. All abbreviations should be explained in footnotes or in headings, e.g. PRN, PRN-Audit, and PARS in Table 1, 6a and 6b.

Answer:
We revised the texts and explained all abbreviations in footnotes.

Table 2b: Give the categories names that are more informative. Here again, the reader needs to read the text in order to understand that “usual care” means “deviation from usual care” and that “guidelines” means that guidelines were either not followed, or that local protocols were missing.

Answer:
We followed your advice

Table 2a: As much as 53% of cases had 1 or more SSF. This should allow for a more detailed categorization, based on the distribution of numbers of SSFs per case. The wording of Table 2a's heading need to be corrected. (e.g.Number of substandard factors (SSF) per case in term perinatal mortality.)

Answer:
We followed your advice.

Table 3: Tulip-classification of UNDERLYING CAUSE OF DEATH in term perinatal mortality cases, by main group and placental subgroup (2010-2012)

Answer:
Table 3 is adapted with extension of ReCoDe and Wigglesworth/Hey and we revised the text.

Table 5: "care type supervision at start of labour". Do you mean Level of care at start of labour? Does primary care include home delivery? If so, this should be noted in footnotes, and probably also in the Methods (the Netherlands has a large proportion of home deliveries compared to many other European countries).

Answer:
Yes, we meant level of care at start of labour. Indeed home deliveries are included for primary care. We noted this in the method section.

There are many tables. The authors might consider showing some results, for instance Tables 2a and b as a figure, for instance a bar chart, (but as mentioned for 2a, with more categories of SSFs)

Answer:
We tried to make a figure of table 2a and b, but this was not very attractive, especially after extension of the table with more categories of SSF's.

I miss some more details, perhaps as a table (if some of the present tables could be changed to figures) about the links between the SSFs and the recommendations made to improve quality of care. A total of 603 recommendations were given, and it would be interesting to see these grouped and tabulated, and the relations between the SSFs and the recommendations discussed.

Answer:
The links between the SSFs and the recommendations would need more than a table. On the website of PAN all recommendations are extensively elaborated http://www.perinataleaudit.nl/onderwerpen/204/uitwerking-van-aanbevelingen . We added this link in the results section.
Otherwise we can't change one of the other tables to figures for more clear results.

Term perinatal death actually also includes post term (23 post term deaths).

Answer:
We have mentioned this now in the method section.

The paper is inspiring, and it is impressing that the Netherlands has managed to get a national, systematic perinatal audit running throughout the country, where all perinatal cooperation groups participate. There is no mentioning about the cost of this program; that might be of interest. What about future plans: continuation, expansion to other indicators, evaluation?
The paper needs language editing, and the tables need improvement. The authors should also consider to use figures instead of tables for some results, and also consider to tabulate groups of recommendations given.
I also miss some discussion about the distribution of causes of death compared to other studies on causes of term perinatal death.
The authors use the wording "term perinatal mortality", while in fact, also post term cases are included. This should be commented in the Methods.

Finally, I would not state in the conclusion of the abstract that the audit possibly has contributed to the decrease in perinatal mortality without testing the significance of the decrease.

Answer:
Funding
PAN receives annual funding from the Ministry of Health of about €900.000. A third is used for support of the PCG's by the regional teams. About 30% is intended for use and management of the registration systems and for reporting and communication (both including personnel costs). Another third is needed for the PAN office, board and advisory committees. This text is added in the introduction section.

Future plans
For the years 2013, 2014 and 2015 the focus is term intrapartum and neonatal death and admission to a neonatal intensive care unit for neonatal asphyxia. This text is added in the introduction section.

The other questions are answered earlier. The decrease of perinatal mortality is tested and the results are written in table 1.

Reviewer: 3
Reviewer Name Babill Stray-Pedersen
Institution and Country Institute of clinical Medicine, University in Oslo
and Division Women and children, Rikshospitalet, Oslo University Hospital
Oslo Norway
Please state any competing interests or state 'None declared': None

The report from this new perinatal mortality audit registry is very interesting and deserves to be published. The study design is appropriate, and clearly described, but the results suffer from lack of proper statistics. and some statement are sort of misleading.
In the abstract and results the declines observed are not significant. No p-values are given. The total term perinatal mortality increases from 2010 to 2011 and then falls. Actually the reduction in perinatal mortality from 2010/2011 to 2012 is significant (p=0.04), however a Type II error has been performed. A simple power calculation reveals a lack of sufficient power ($1-\beta = 0.3$) to presume a significant reduction in perinatal mortality.
There are too many tables, some has the same information (like Table 2 and 4). The denominators are not given – only numbers and percentages making it difficult to calculate if there are real differences. The headings of the tables are also lacking accurate information. Some refers to PARS, some to PRN-Audit. Abriviations are lacing in the tables

Table 1. no significance given

Answer: we added p-values (Chi-square test) in table 1

Table 2a: Delete, all information given in Table 4.

Answer:
Table 2a is now more complete with number of cases with 1 SSF, 2 SSF, 3SSF, 4SSF and ≥5SSF and now not all information is given in table 4

table 2b: There are 10 cases with more SSF, how does this show in the percentage??

Answer:

The 717 SSF's are present in 376 cases, so there were more than 10 cases with more SSF. We think that the corrected table 2a together with 2b is useful and not easy to combine with the adapted table 4 with relation to death over the years.

Table 3. Autopsies were performed in 269 cases(38%) only and placenta biopsies in 544 cases(77%). How does this reflect in the table??

Answer:
The number of autopsies and placental examinations is registered in PRN-Audit and not in PARS. Table 3 is a result from PARS. So we can't give the relation of performed autopsies and placenta examination to the results of death classifications in table 3.

Table 4 gives information from PARS first part same as table 2. Probable relation to death per year: denumerators are lacking.

Answer:
We made a new table 2 and table 4 with denominators. Table 4 is extended with relation to death for all categories per year and with p-values for trends (Chi-square test).

Table 5 refer to PRN-audit data. Denominator in Primary care is lacking, but my calculation shown the trend is not significant. To state that it is a 24% decrease is sort of giving a wrong impression.

Answer:
You are right that the trend in primary care at start of labour is not significant (probably by low numbers) and 24% decrease gives indeed a wrong impression.
We added denominators and the p-values (Chi-square test) in the table.
However the trend for secondary care at start of labour is significant (p=0.001).
We have adapted the text in the abstract, results and discussion section.

Table 6a and b: why not in one table PRN,PARS and PRN -Audit?? The same information are given twice. Why is gestational age recorded differently.

Answer:
It is impossible to make one table because PARS and PRN-Audit are separate databases and impossible to link. In PARS is a limited set of data available such as gestational age only classification 37.0-40.6 and ≥41.0 weeks, no data of birth weight, no data of ethnicity and maternal age.
In PRN-Audit much more data are registered and these are compared with PRN data separately.

6a: Total numbers in PARS and PRN are lacking.

Answer:
Total numbers are added.

6b: any relationship between non-Caucasian ethnicity and birth weight <2000g??
How is fetal spelled???

Answer:
We did not analyse any relationship in characteristics. The goal of the table was to investigate potential bias in the distribution of characteristics in PRN-Audit and PARS compared to the national perinatal database PRN.
The spelling of fetal is edited in the text

VERSION 2 – REVIEW

REVIEWER	Kari Klungsøyr Department of Global Public Health and Primary Care, University of Bergen, Norway
REVIEW RETURNED	01-Sep-2014

GENERAL COMMENTS	In this revised version of their manuscript, the authors have answered most of my previous comments. My main comment now is that I still think the manuscript needs language editing. There are still several grammatical errors, and a number of sentences need rephrasing,- e.g. page 35 line 9-10; page 36 lines 21-27 and lines 34-38, and others. The authors should further be more consistent in their use of "cases of term perinatal mortality" or "cases of term perinatal deaths" (or as I suggested: "term perinatal deaths"). Page 31, line 38: The authors have deleted "deviation" in "deviation of usual care" and replaced with "nonobservance of usual professional care". Further down, line 46, the original wording ("deviation of usual care") is unchanged. "Nonobservance of usual professional care" is not a good English description (it is also used in the abstract and in Table 2b),- here I would suggest keeping "deviation FROM usual professional care". Whatever is chosen, it should be used consistently. On page 35, line 15, the authors say "….further training of the audit teams in using the Tulip classification APART FROM the desirability of more autopsies…..". I guess they mean "using the Tulip classification IN ADDITION TO the desirability of more autopsies…? Other comments: Page 13, line 39-40: I would suggest adding a further evaluation of time trends as an important focus for the years 2013-15. The "time trend" evaluation so far is based on only three years, which is too short to draw conclusions about trends in a rare outcome. Tables: The authors have – as requested – included results from statistical tests, which is good. Are the chi square tests overall tests, or a comparison between 2012 and 2010? As noted, I think the revision which is needed now is language editing, therefore I do not think I need to see the manuscript again. As previously commented, I think the paper is inspiring to read, and it is impressive that the Netherlands has managed to get this national systematic perinatal audit running throughout the country. If further evaluation of time trends in term perinatal mortality still show reductions in rates, this must be very encouraging.

REVIEWER	Stray-Pedersen, Babill Div Women and Children, Rikshospitalet and Institute of Clinical Medicine, University of Oslo, Norway
REVIEW RETURNED	08-Sep-2014

GENERAL COMMENTS	All previous review comments are now corrected or explained in detail.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
Reviewer Name Kari Klungsøyr
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Please state any competing interests or state 'None declared': None declared

In this revised version of their manuscript, the authors have answered most of my previous comments. My main comment now is that I still think the manuscript needs language editing. There are still several grammatical errors, and a number of sentences need rephrasing,- e.g. page 35 line 9-10; page 36 lines 21-27 and lines 34-38, and others. The authors should further be more consistent in their use of "cases of term perinatal mortality" or "cases of term perinatal deaths" (or as I suggested: "term perinatal deaths"). Page 31, line 38: The authors have deleted "deviation" in "deviation of usual care" and replaced with "nonobservance of usual professional care". Further down, line 46, the original wording ("deviation of usual care") is unchanged. "Nonobservance of usual professional care" is not a good English description (it is also used in the abstract and in Table 2b),- here I would suggest keeping "deviation FROM usual professional care". Whatever is chosen, it should be used consistently. On page 35, line 15, the authors say "….further training of the audit teams in using the Tulip classification APART FROM the desirability of more autopsies…..". I guess they mean "using the Tulip classification IN ADDITION TO the desirability of more autopsies…?

Answer:
We performed language editing and especially followed your advice for consistent use of "term perinatal deaths", "deviation FROM usual professional care"and "using the Tulip classification IN ADDITION TO the desirability of more autopsies.

Other comments:
Page 13, line 39-40: I would suggest adding a further evaluation of time trends as an important focus for the years 2013-15. The "time trend" evaluation so far is based on only three years, which is too short to draw conclusions about trends in a rare outcome.

Answer:
We followed your suggestion for term perinatal mortality time trend evaluation for the years 2013-15 in the section Implications of the study and further research.

Tables: The authors have – as requested – included results from statistical tests, which is good. Are the chi square tests overall tests, or a comparison between 2012 and 2010?

Answer:
For testing group differences we used a chi-squared test; we did not test differences between 2012 and 2010.

As noted, I think the revision which is needed now is language editing, therefore I do not think I need to see the manuscript again. As previously commented, I think the paper is inspiring to read, and it is impressive that the Netherlands has managed to get this national systematic perinatal audit running throughout the country. If further evaluation of time trends in term perinatal mortality still show reductions in rates, this must be very encouraging.

Answer:
We agree.